COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10-VIII-2006
C(2006) 3721

NOT FOR PUBLICATION

COMMISSION DECISION

of 10-VIII-2006

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Thelin - Sitaxentan sodium", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 10-VIII-2006

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Thelin - Sitaxentan sodium", an orphan medicinal product for human use

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Encysive (UK) Limited on 17 August 2005 under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 1 June 2006,

Whereas:

(1) Commission Decision C(2004)4225 of 21 October 2004, adopted in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[3] designated "Sitaxentan sodium" as an orphan medicinal product.

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).
[2] OJ L 136, 30.4.2004, p. 1
[3] OJ L 18, 22.1.2000, p. 1.

(2) "Thelin - Sitaxentan sodium" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(3) The marketing authorisation should be subject to compliance with conditions, set out in Annex II to this decision. The implementation of certain of these conditions with regard to the safe and effective use of the medicinal product is to be ensured by the Member States, in accordance with Article 127a of Directive 2001/83/EC. To this effect, Commission Decision C(2006) 3722 of 10-VIII-2006 is simultaneously being addressed to the Member States.

(4) It is therefore appropriate to authorise its placing on the market.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the orphan medicinal product "Thelin - Sitaxentan sodium", the characteristics of which are summarised in Annex I to this Decision. "Thelin - Sitaxentan sodium" shall be registered in the Community register of medicinal products under Nos:

EU/1/06/353/001 Thelin-100 mg-Film-coated tablet-Oral use-blister (PVC/Aclar/alu)-14 tablets

EU/1/06/353/002 Thelin-100 mg-Film-coated tablet-Oral use-blister (PVC/Aclar/alu)-28 tablets

EU/1/06/353/003 Thelin-100 mg-Film-coated tablet-Oral use-blister (PVC/Aclar/alu)-56 tablets

EU/1/06/353/004 Thelin-100 mg-Film-coated tablet-Oral use-blister (PVC/Aclar/alu)-84 tablets

EU/1/06/353/005 Thelin-100 mg-Film-coated tablet-Oral use-bottle (HDPE)-28 tablets

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, 10-VIII-2006

For the Commission
Heinz ZOUREK
Director-General